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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/591,817 | 09/06/2006 | Makoto Taketo | 2006_1487A | 3081 |
| 513 7590 06/24/2010 WENDEROTH, LIND & PONACK, L.L.P. 1030 15th Street, N.W., Suite 400 East Washington, DC 20005-1503 | | | EXAMINER | |
| | | | YAO, LEI | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1642 | |
| | | | | |
| | | | NOTIFICATION DATE | DELIVERY MODE |
| | | | 06/24/2010 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ddalecki@wenderoth.com eoa@wenderoth.com

| | Application No. | Applicant(s) | | | | |
|--|---|-----------------|--|--|--|--|
| Office Action Comments | 10/591,817 | TAKETO ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | LEI YAO | 1642 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| Status | | | | | | |
| 1)⊠ Responsive to communication(s) filed on <u>05 Ma</u> | av 2010. | | | | | |
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| · = | , | | | | | |
| · | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | |
| Disposition of Claims | | | | | | |
| 4)⊠ Claim(s) <u>1-10,12 and 14-19</u> is/are pending in th | ne annlication | | | | | |
| 4a) Of the above claim(s) <u>1-9,14,17 and 19</u> is/are withdrawn from consideration. | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6)⊠ Claim(s) <u>10, 12, 15-16 and 18</u> is/are rejected. | | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | |
| 8) Claim(s) are subject to restriction and/or | election requirement | | | | | |
| | oloodon roquiromona. | | | | | |
| Application Papers | | | | | | |
| 9)☐ The specification is objected to by the Examiner | | | | | | |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | |
| 11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12)⊠ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a)□ All b)⊠ Some * c)□ None of: | | | | | | |
| 1. Certified copies of the priority documents | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| | | | | | | |
| Attachment(s) | | | | | | |
| 1) Notice of References Cited (PTO-892) | 4) Interview Summary | | | | | |
| 2) DNotice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Da | ite | | | | |
| 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date | 5) Notice of Informal Page 6) Other: | акент Аррисаноп | | | | |
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Response to Amendment and Arguments

The Amendment filed on 5/6/2010 in response to the previous Non-Final Office Action (11/6/2010) is acknowledged and has been entered.

Claims 11 and 13 are cancelled.

Claims 1-10, 12, and 14-19 are pending.

Claims 1-9, 14, 17 and 19 have been withdrawn from consideration as nonelected invention.

Claims 10, 12, 15-16 and 18, drawn to a method of treating or preventing lymph node metastasis to the extent of intestine, breast and melanoma cancers comprising administering a composition comprising CXCR3 inhibitor (elect antibody to CXCR3), are under consideration.

Applicant has elected using an antibody as an antigonist (inhibitor) of CXCR3 for examination of a method of treating cancer metastasis in the response to the restriction requirement of June 24, 2009. Then after the non-final Office action issued applicant requested to examine the method of using anti-CXCR3 ligand antibody during the interview on February 17, 2010. In the most recent remarks response to the non-final Office action filed May 6, 2010, Applicant asks that anti-CXCR liagnad antibody be examined upon allowance of the elected species (page 5, line 5 from bottom). Applicant's request is considered and the species of anti-CXCR liagnad antibody will be searched and examined when the allowable subsject is established.

Rejections/Objection Withdrawn

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1. The objection of claims 10-13, 15-16, and 18, as being depending on non-examined claim 1, is withdrawn in view of amendment to or cancellation of the claims.

- 2. The rejection of claims 10, 13, 15-16 and 18 under 35 U.S.C. 112, first paragraph, scope of enablement, is withdrawn in view of the amendment to or cancellation of the claims.
- 3. The rejection of claims 10, 12, 15, 16 and 18 under 35 U.S.C. 102(b) as being anticipated by Burns et al (Pub No. US 20030124628) is withdrawn in view of amending the base claim 10 currently reciting treating or preventing lymph node metastasis of CXCR3-expressing cancer.
- 4. The rejection of claims 10, 12, 15, 16 and 18 under 35 U.S.C. 103(a) as being unpatentable over Kawada et al (Cancer Res), or Goldberg-Bittman et al (Immu Lett) in view of Levanon et al (US 20050152906) is withdrawn in view of providing English translation of Japan 2004-065612 filed on 3/9/2004. However, the rejection as being unpatentable over Robledo et al (JBC, 2001) in view of Levanon et al (US 20050152906, effective filing June 2003) is maintained (see below).

Rejections Maintained and Response to Arguments

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 1. Claims 10, 12, 15, 16 and 18 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Burns et al (Pub No. US20030124628, pub date. July 3, 2003), in view of Blake Cady (Arch Surg, vol 119, page 1067-1072. 1984).

Response to Applicant's argument:

Applicant argues that Burn et al suggest that chemokines are involved in cancer metastasis, mention CXCR3 as one of the chemokine receptors, and that CXCR4 is

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involved in breast cancer metastasis, does not mention CXCR3 in relation to cancer metastasis (page 6, art rejection).

Applicant further states that the specification demonstrates that <u>CXCR3</u> does not affect metastasis to lung and liver (page 6, last line). Applicant then provides a reference by Saur et al and argues that the reference shows that <u>CXCR4</u>, but no CXCR7, is involved in liver and lung cancer metastasis.

Applicants' arguments have been carefully considered but are not persuasive. Applicant's argument is based on the observation of the instant specification and reference of Saur et al on that CXCR3 is NOT involved in LIVER and LUNG metastasis. The argument is irrelevant to the currently claimed invention that is drawn to lymph.node metastasis of CXCR3 expressing cancer. As stated above, Burn et al suggest that chemokine is involved in cancer metastasis and mention CXCR3 as one of chemokine receptor, but not specify the metastasis to lymph node. Applicant is reminded the Office made the rejection under 35 U.S.C. 103(a) is based on the guideline of MPEP 2141 (rejection under 35 USC 103), particularly, MPEP 2141.02, which states

In determining the difference between the prior art and the claims, the question under 35 USC103 is not whether the difference <u>themselves</u> would have been obvious, but whether the claimed invention <u>as a</u> whole would have been obvious.

According, it is improper to argue and discuss the references cited under USC 103 rejected individually without clearly addressing the combined teachings. It must be remembered that the references are relied upon in combination and are not meant to be considered separately. Thus, in this case, Burn et al teach and suggest that CXCR3 is a chemokine receptor involved in metastasis of breast cancer, but not specify where to

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metastasize. The second reference by Cady teaches breast, melanoma, and colon cancers are often metastasized to lymph node. Thus, one skilled in the art would combine the teaching of Burn and Cady to arrive at the instant invention that is to block an activity of CXCR3 by an anti-CXCR3 antibody, which would be used for treating or preventing the cancer cell metastasizing to the lymph node. Thus, Applicant's arguments have not been found persuasive, and the rejection is maintained.

2. Claims 10 and 12, 15, 16 and 18 remain rejected under 35 U.S.C. 103(a) as being unpatentable Robledo et al (JBC, vol 276, page 45098-105, 2001) in view of Levanon et al (US 20050152906, priority to June 2003). The rejection is remained because primary references are used in the rejection as alternatives (Robledo or Kawada or Goldberg-Bittman, see above rejection withdrawn). The English translation of the foreign priority document renders the references of Kawada et al (Cancer Res. Vol 64, page 4010-17, June 2004) and Goldberg-Bittman et al (Immu let, vol 93, page 171-178, March, 29, 2004) no longer being prior arts, but the claimed invention are still unpatentable over Robledo et al (2001) in combination with Levanon et al (filing 2003) as stated in the rejection. Applicant does not provide argument for the teachings of these two references.

Conclusion

No claim is allowed.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to <u>Lei Yao</u>, whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-6.00pm Monday-Thursday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Lei Yao/ Examiner, Art Unit 1642

/Larry R. Helms/ Supervisory Patent Examiner, Art Unit 1643